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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/626,617	07/27/2000	Laure Dumoutier	LUD 5664 US	9662

24972 7590 12/26/2001  
FULBRIGHT & JAWORSKI, LLP  
666 FIFTH AVE  
NEW YORK, NY 10103-3198

EXAMINER
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DECLoux, AMY M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 12/26/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/626,617

Applicant(s)  
Dumoutier et al.

Examiner  
DeCloux, Amy

Art Unit  
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on Sep 28, 2001

2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 1-12 is/are pending in the application

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☒ Claims 1-12 are subject to restriction and/or election requirements

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some\* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20) ☐ Other:

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### Detailed Action

1. Applicant's amendment, mailed 9-28-2001 (Paper No. 9), is acknowledged. Claims 1-12 are pending.
2. The rejections of record can be found in the previous Office Action mailed 7-6-01 (Paper No. 8).
3. The following is a quotation of the first paragraph of 35 U.S.C. § 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. MAINTAINED Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for stimulating expression of a STAT3 and STAT1 comprising contacting a cell capable of said expression with an amount of human IL-TIF/IL-21, and a method for stimulating expression of a STAT3 and STAT5 comprising contacting a cell capable of said expression with an amount of murine IL-TIF/IL-21, does not reasonably provide enablement for the broader recitation of a method for stimulating expression of any STAT transcription factor comprising contacting a cell capable of said expression with an amount of any IL-TIF/IL-21. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. .

Applicant has commented on the Examiner's use of references that "postdate" Applicant's effective filing date. Such references are appropriate to serve as published art-recognized references to support the Examiner's position in the rejection and for showing the state of the art with regards to particular problems or known facts that indicate that a problem still exists or that treatments are still unpredictable in the art at a later date or even the present time. Further, the examiner notes that the specification must be enabling as of the filing date. It is noted that post-filing date references can be used as evidence of the state of the art existing on the filing date of the application. See MPEP 2164.05(a), including In re Hogan , 194 USPQ 527 (CCPA 1977) and In re Wright , 27 USPQ2d 1510 (Fed. Cir. 1993).

As stated in In re Wright 27 USPQ2d 1510, 1512 (CAFC 1993), the issue is now what the state of the art is today or what a skilled artisan today would believe, but rather what the state of the art at the time of filing and what a skilled artisan would have believed at that time. Hybritech Inc. v. Monoclonal Antibodies, Inc. 802 F2d 1367, 1384, 231 USPQ 81,

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94 (Fed. Cir.), cert denied, 480 U.S. 947 (1987); In re Hogan, 559 F2d 595, 604, 194 USPQ 527, 535 (CCPA 1977).

It is noted that said reference teaches on page 10146, column 2 that recombinant human IL-TIF activated the transcription factors STAT-3 and to a lesser extent STAT-1, and not STAT-5, consistent with what is disclosed in the instant specification on page 30..

Furthermore, as stated in the previous office action, the instant specification discloses in Example 21 that murine IL-TIF/IL-21 stimulates STAT3 and STAT 5 but not STAT 1. So clearly not all IL-TIF/IL21 can stimulate any STAT transcription factor. In view of the unpredictability of the art in this area, a higher degree of enablement is required.

Applicant has argued that the decisions in Hogan and Koller prevent the examiner from using post-dating references for showing lack of enablement. The examiner's position is that the fact situation in these cases is not relevant. First of all, the examiner has relied upon applicant's own disclosure (pages 30 and Example 21) for showing enablement is not commensurate with the scope of the claims. Clearly applicant's own disclosure does not post date the filing date. Further all of the recited types of STAT proteins and IL-TIF/IL21 proteins were available at the time of filing. Thus the instant situation does not fit with Hogan wherein enablement was lacking for production of a material not known at the time of filing. Koller pertains to interpretation of claim language based upon post filing date references; claim interpretation is not an issue instantly.

Therefore, though applicant's arguments have been carefully considered, they are not deemed persuasive and the rejection is maintained essentially for the reasons of record.

5. MAINTAINED Claims 8-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for inducing production of acute phase proteins human serum amyloid A1, alpha chymotrypsin and haptoglobin in a liver cell by human or murine IL-TIF/IL-21, does not reasonably provide enablement for the broader recitation of a method for for inducing production of any acute phase proteins in any cell type by any IL-TIF/IL-21. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicants traverse the rejection on the grounds that the examiner has not drawn any correlation between the alleged lack of enablement for STAT expression and acute phase proteins. However, the examiner points out that the rejection is not based upon any one acute phase protein, but instead upon the lack of enablement for method comprising the combination of the broader recitation of a method for for inducing production of any acute phase proteins in any cell type by any IL-TIF/IL-21. Because said STAT transcription factors (such as STAT 3) ultimately effect the inducement of acute phase

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proteins (see last paragraph of column 2 of page 10146 of said post-filing date reference, it is not clear what effects any IL-TIF/IL21, as stated above, has on any cell type in terms of inducing acute phase proteins.

Therefore, though applicant's arguments have been carefully considered, they are not deemed persuasive and the rejection is maintained essentially for the reasons of record.

6. No claim is allowed.


7. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.  
Patent Examiner,  
Group 1640, Technology Center 1600  
December 20, 2001

  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 182/1644